BORA LASKIN LAW LIBRARY
3 1761 04854 9711

REGULATORY AND ETHICAL ISSUES IN MEDICAL RESEARCH AND DRUG DEVELOPMENT

VOLUME II

PROFESSOR TRUDO LEMMENS

With the able assistance of Ikka Delamer and Vanessa Kee

FACULTY OF LAW

UNIVERSITY OF TORONTO

FALL 2000

(for internal use by students)

Storage

K
3601
.A58L45
2000
v.2
c.1

BORA LASKIN LAW LIBRARY
AUG 17 2000
FACULTY OF LAW
UNIVERSITY OF TORONTO

REGULATORY AND ETHICAL ISSUES IN MEDICAL RESEARCH AND DRUG DEVELOPMENT

VOLUME II

PROFESSOR TRUDO LEMMENS

With the able assistance of Ikka Delamer and Vanessa Kee

FACULTY OF LAW

UNIVERSITY OF TORONTO

FALL 2000

(for internal use by students)

VOLUME II

V. The Content of REB Review; Risk Assessment; Value and Validity; Monitoring Research

Freedman, Benjamin et al., "Demarcating Research and Treatment: A Systematic Approach for the Analysis of the Ethics of Clinical Research" (1992) 40 *Clinical Research* 653-660. **253**

Kopelman, L., "Estimating Risk in Human Research" (1981) 29 *Clinical Research* 1-8. **261**

Freedman, Benjamin. "Scientific Value and Validity as Ethical Requirements for Research: A Proposed Explication" (1987) 9(6) *IRB: A Review of Human Subjects Research* 7-10. **269**

Weijer, C., et al., "Monitoring Clinical Research: An Obligation Unfulfilled" (1995) 152 *Canadian Medical Association Journal* 1973-1980. **273**

Heath, Erica. "The IRB's Monitoring Function: Four Concepts of Monitoring" (1979) 1(5) *IRB: A Review of Human Subjects Research* 1-12. **281**

Emanuel, Ezekiel J., *et al.*, "What makes clinical research ethical?" (2000) 283(20) *Journal of the American Medical Association (JAMA)* 2701-2711 **285**

VI. The Ethics of Clinical Trial Design

Freedman, Benjamin. "Equipoise and the Ethics of Clinical Research." (1987) 317 *New England Journal of Medicine* 141-145. **296**

Hellman, Samuel and Deborah S. Hellman, "Of Mice but not Men: Problems of the Randomized Clinical Trial" (1991) 324 *New England Journal of Medicine* 1585-1589. **301**

Passamini, Eugene, "Clinical Trials – Are They Ethical?" (1991) 324 *New England Journal of Medicine* 1589-1592. **305**

Freedman, Benjamin *et al.*, "Placebo Orthodoxy in Clinical Research I: Empirical and Methodological Myths" and "Placebo Orthodoxy in Clinical Research II: Ethical and Legal and Regulatory Myths" (1996) 24(3) *Journal of Law, Medicine & Ethics* 243-259. **308**

VII. Informed Consent and Challenges to Informed Consent

Donagan, Alan, "Informed Consent in Therapy and Experimentation." (1977) 2 *Journal of Medicine and Philosophy* 307-329. **325**

Addicott, Christian D., "Regulating Research on the Terminally Ill: A Proposal for Heightened Safeguards" (1999) 15 *Journal of Contemporary Health Law and Policy* 479-524. **337**

Dickert, Neal and Grady, Christine, "What's the Price of a Research Subject? Approaches to Payment for Research Participation." (1999) 34 *New England Journal of Medicine* 198-203. **361**

Lemmens, Trudo and Elliot, Carl, "Guinea Pigs on the Payroll: The Ethics of Paying Research Subjects." (1999) 7 *Accountability in Research* 3-20. **366**

Moreno, John. "Captive and Convenient Populations" in Jeffrey Kahn et al. (eds) *Beyond Consent* (New York: Oxford University Press, 1998) 111-130. **376**

Freedman, Benjamin *et al.*, "In Loco Parentis: Minimal Risk as an Ethical Threshold for Research upon Children." (March-April 1993) *Hastings Center Report* 13-19. **387**

Elliot, Carl, "Caring About Risks" (1997) 54 *Archives of General Psychiatry* 113-116. **394**

Weiss Roberts, Laura, "The Ethical Basis of Psychiatric Research: Conceptual Issues and Empirical Findings" (1998) 39 *Comprehensive Psychiatry* 99-110. **398**

VIII. Selection of Subjects and Justice; Research Involving Communities

Dresser, Rebecca, "Wanted: Single, White Male for Medical Research" (January-February 1992) *Hastings Center Report* 24-29. **410**

Charo, R.A., "Protecting Us to Death: Women, Pregnancy, and Clinical Research Trials" (1993) 38(1) *Saint Louis University Law Journal* 135-187. **416**

Weijer, Charles, "Evolving Ethical Issues in Selection of Subjects for Clinical Research" (1996) 5 *Cambridge Quarterly of Healthcare Ethics* 334-45. **443**

Weijer, Charles, *et al.*, "Protecting Communities in Research: Current Guidelines and Limits of Extrapolation" (1999) 23(3) *Nature Genetics* 275-80. **445**